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Serial No.: 10/626,142

Confirmation No.: 9324

Filed: July 24, 2003

For: DENTAL WHITENING COMPOSITIONS AND METHODS**Remarks**

The Office Action mailed 13 October 13 2006 and the Advisory Action mailed 28 February 2007 have been received and reviewed. Claims 1, 15, 23, 30, 41, 46-52 having been amended, claims 4, 18, 26, 33, 44 having been canceled, without prejudice, and no claims having been added, the pending claims are claims 1-3, 5-17, 19-25, 27-32, 34-43, and 45-80.

Independent claims 1, 15, 23, 30, and 41 have been amended to incorporate the language of dependent claims 4, 18, 26, 33, 44, respectively (all now canceled). Independent claims 46, 48-50, and 52 have been amended to incorporate similar language.

Independent claims 47 and 51 have been cosmetically amended to state that the coating includes greater than 10% by weight of a tooth whitening agent, based on the total weight of the coating, not the dental whitening composition.

Reconsideration and withdrawal of the rejections are respectfully requested.

**Rejection under 35 U.S.C. §112, First Paragraph**

In the Final Office Action mailed 13 October 2006, the Examiner rejected claims 1-6, 8-12, 14-20, 22-27, 29, 46-49, and 57-72 under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants thank the Examiner for indicating in the Advisory Action mailed 28 February 2007 that the rejection under 35 U.S.C. §112, first paragraph, has been withdrawn as a result of the Response filed 13 December 2006.

**Rejection under 35 U.S.C. §102**

The Examiner rejected claims 1-3, 23-25, 30-32, 46, 49-50, 53-56, and 65-72 under 35 U.S.C. §102(b) as being anticipated by EP 0363095 A2 to Minnesota Mining and Manufacturing Company. This rejection is respectfully traversed.

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Independent claims 1, 23, and 30 have been amended to incorporate the language of dependent claims 4, 26, and 33, respectively (all now canceled). For at least the reason that claims 4, 26, and 33 are not anticipated by EP 0363095 A2, Applicants respectfully submit that independent claims 1, 23, and 30 (as amended), along with dependent claims 2-3, 24-25, 31-32, 53-56, and 65-72, also are not anticipated by EP 0363095 A2.

Independent claims 46 and 49-50 were amended to incorporate similar language. For at least this reason, Applicants respectfully submit that claims 46 and 49-50 are not anticipated by EP 0363095 A2.

Reconsideration and withdrawal of the rejection under 35 U.S.C. §102 are respectfully requested.

**Rejections under 35 U.S.C. §103**

The Examiner rejected claims 1-80 under 35 U.S.C. §103(a) as being unpatentable over EP 0363095 A2 to Minnesota Mining and Manufacturing Company and further in view of Huang et al. (U.S. Patent No. 6,083,421). Applicants respectfully traverse the rejection.

"To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure." M.P.E.P. §2142.

As motivation for combining EP 0363095 reference with Huang et al., the Examiner asserted that "[o]ne skilled in the art would be motivated to combine the EP 0363095 reference with Huang et al. since *both are directed to teeth whitening compositions* comprising peroxides

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which can be applied as a topical coating" (page 10, last paragraph, of the Office Action mailed 13 October 2006; emphasis added). Applicants respectfully disagree.

First, Applicants earnestly disagree with the Examiner's characterization of EP 0363095 A2 as being "directed to teeth whitening compositions." In contrast, EP 0363095 A2 explicitly states the following:

The present invention relates to compositions which are capable of releasing fluoride ions. More specifically, this invention relates to dental compositions and articles which contain an organic-soluble fluoride source(s) and are capable of releasing fluoride ion into the surrounding tissue. Further, the invention relates to a method of inhibiting the progression of and/or preventing dental caries.  
(Page 2, lines 4-7).

Applicants respectfully submit that EP 0363095 A2 not only lacks adequate disclosure to support the Examiner's rejection, EP 0363095 A2 is in fact *totally silent regarding teeth whitening compositions*. The Examiner is reminded that in evaluating lack of disclosure regarding an obviousness rejection, the Court of Customs and Patent Appeals has stated that "[s]ilence in a reference is hardly a proper substitute for an adequate disclosure of facts from which a conclusion of obviousness may justifiably follow." (*See In re Burt and Walter*, 148 U.S.P.Q. 548, 553 (C.C.P.A. 1966).

Second, the Examiner stated that "the EP 0363095 reference teaches peroxides which after application to the tooth are exposed to light" (page 10 of the Final Office Action mailed 13 October 2006). EP 0363095 A2 clearly discloses *the combination of a monomer with a peroxide*, which after application to the tooth, can be exposed to light. However, Applicants' Representatives could find no disclosure or suggestion of *the combination of a polymer with a peroxide*, which after application to the tooth, can be exposed to light.

Nonetheless, the Examiner asserted that "absent a teaching of purity of product during each step in the process of making the product, the product taught in the reference must

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*necessarily* contain residual peroxide" (page 2 of the Advisory Action mailed 28 February 2007; emphasis added). Applicants earnestly disagree.

Applicants respectfully disagree with the Examiner's unsupported assertion that a polymer prepared using a peroxide initiator must *necessarily* contain residual peroxide. For example, Applicants respectfully submit that one of skill in the art would recognize that polymerization conditions can be envisioned in which the peroxide initiator is consumed during the initiation process. *See, for example*, Kirk-Othmer Concise Encyclopedia of Chemical Technology, John Wiley & Sons, Inc., page 648 (1985), stating that "[i]nitiators are chemical substances or energy sources that are used to initiate a chemical reaction and that are *consumed* during the initiation process" (emphasis added). Thus, Applicants respectfully submit that a polymer prepared using a peroxide initiator does *not necessarily* contain residual peroxide.

Moreover, independent claims 1, 15, 23, 30, 41, 46, 48-50, and 52 (as amended) each recite, among other things, that the composition includes about 0.05% by weight to about 50% by weight of the tooth whitening agent, based on the total weight of the tooth whitening agent and the polymer. Independent claims 8, 37, 47, and 51 each recite, among other things, that the composition or coating includes greater than 10% by weight of a tooth whitening agent, based on the total weight of the dental whitening composition or coating, respectively. Applicants respectfully submit that even if a polymer prepared using a peroxide initiator arguably did contain residual peroxide, EP 0363095 A2 provides no teaching or suggestion that the peroxide would be present at the presently claimed levels and function as a tooth whitener.

For at least the foregoing reasons, Applicants respectfully submit that the Examiner has failed to establish motivation, absent Applicants' present disclosure, for combining EP 0363095 A2 with Huang et al. Thus, Applicants respectfully submit that the Examiner has failed to establish a *prima facie* case of unpatentability of claims 1-80 over EP 0363095 A2 in view of Huang et al.

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The Examiner rejected claim 35 under 35 U.S.C. §103(a) as being unpatentable over EP 0363095 A2 to Minnesota Mining and Manufacturing Company as applied to claims 1-80 above taken with Lakshmanan (U.S. Patent No. 4,018,732). Applicants respectfully traverse the rejection.

The deficiencies of EP 0363095 A2 as applied to claim 30 have been discussed herein above. For similar reasons, Applicants respectfully submit that the Examiner has failed to establish motivation, absent Applicants' present disclosure, for combining EP 0363095 A2 with Lakshmanan. Notably, the Examiner's assertion that "[o]ne of skill in the art would be motivated to combine the EP 0363095 reference with Lakshmanan and as combined would make the above claim obvious" appears, on its face, to be an impermissible use of Applicants' disclosure as a template for hindsight reconstruction.

Moreover, Lakshmanan fails to provide that which is missing from EP 0363095 A2. For example, Applicants' Representatives were unable to locate any teaching or suggestion of a tooth whitening agent or a peroxide in Lakshmanan. Thus, even if one arguably had motivation to combine Lakshmanan with EP 0363095 A2, one would not arrive at Applicants' invention.

For at least these reasons, Applicants respectfully submit that the Examiner has failed to establish a *prima facie* case of unpatentability for claim 35 being obvious over EP 0363095 A2 in view of Lakshmanan.

Reconsideration and withdrawal of the rejections under 35 U.S.C. §103 are respectfully requested.

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**Summary**

It is respectfully submitted that all the pending claims are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted

By

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*March 28, 2007*

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**CERTIFICATE UNDER 37 CFR §1.8:**

The undersigned hereby certifies that the Transmittal Letter and the paper(s), as described hereinabove, are being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office, addressed to Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 28th day of March, 2007, at 2:40 pm (Central Time).

By: Name: Danielle Maroz